

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Moyer et al.
Application No.: 09/912,072
Filed: July 24, 2001
For: *Identification of Poinsettia Cultivars*

Confirmation No.: 3267
Group Art Unit: 1634
Examiner: S. Bausch

Date: June 30, 2008

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APPELLANTS' REPLY BRIEF ON APPEAL UNDER 37 C.F.R. §41.41

Sir:

Appellants' Reply Brief is filed in response to the Examiner's Answer mailed April 30, 2008. This Reply Brief highlights how the Examiner's Answer continues to fail to establish a *prima facie* case of obviousness in rejecting the pending claims.

For at least the reasons explained in Appellants' Brief on Appeal and the present Reply Brief, Appellants request reversal of the claim rejections and passing of the application to issue.

I. Examiner's Answer – Response to Arguments

The Examiner's Answer repeats the rejections from the Final Office Action, and further adds, at pages 12-32, a "Response to Argument" section. This Reply Brief is submitted to address selected portions of the Response to Argument section of the Examiner's Answer and will not reiterate each of the arguments previously presented in the Appeal Brief.

The Legal Standard of Obviousness is Not Met.

The Examiner states that *KSR International Co. v Teleflex Inc.* (550 U.S. ___, 82 U.S.P.Q.2d 1385 (2007)) (hereinafter *KSR*) "reaffirms the principles of obviousness based in its precedent that the combination of familiar elements according to known methods is likely to be obvious when it does not more than yield predictable results." The Examiner then concludes that the method of using a known method of AFLP to distinguish cultivar diversity was known in the art and taught by Loh et al., Barcaccia et al., Sukwinder et al. or Baker et al. and would have

rendered the predictable result of using AFLP to determine genetic variation in poinsettias. Appellants respectfully disagree.

As an initial point, *KSR* states "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." (*Id.*). Additionally and as specifically set forth throughout the Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*, "[t]he rationale to support a conclusion that the claim would have been obvious is that 'a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success (citing to *KSR*). If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.'" (Federal Register Vol. 72, No. 195, pages 57526-57535, 57534).

Appellants respectfully submit that the Examiner has failed to show that one of ordinary skill in the art would have been motivated to make the suggested combinations or been led to carry out the methods of the claimed invention with any reasonable expectation of success prior to Appellants' own invention. The Examiner has concluded that the use of AFLP would be predictable in poinsettia simply based on several publications showing its use in other plant species and two bacterial species. However, the successful use of any single method of genetic analysis including RAPD, RFLP, SSR, AFLP, or any other method, in a particular species is not predictable based on its success in other species.

The Examiner summarily dismisses evidence provided by Appellants showing unpredictability of these methods by making such statements as "the claims are not drawn to analysis of SSR but by AFLP analysis and SSR analysis is a different technique than AFLP and cannot be used as an indicator for the predictability of AFLP in poinsettia." Examiner's Answer, page 20. Appellants respectfully submit that similar to AFLP, SSR analysis is a known method. Similar to the Examiner's argument with regard to AFLP, the SSR technique has been applied to many species successfully (Russell et al.; Pejic et al.); however, SSR was not successfully applied to poinsettia. (*See* Moyer Declaration). Thus, simply because AFLP has been applied

successfully to such widely divergent plant species as geranium, *Caladium*, rice and willow or the bacterial species of *E. coli* or *B. anthracis*, cannot be the basis for the conclusion of predictability of successful application of AFLP in poinsettia. Accordingly, the outstanding rejections fail to satisfy the Office's burden necessary to maintain an obviousness rejection and should be withdrawn.

A. Claims 1, 3, 5-7, 21, 23, 24, 63 and 69 are not obvious under 35 U.S.C. § 103(a) over Ling et al. (HortSci 32: 122-124 (1997)), in view of Loh et al. (Annals of Bot. 84:155-161 (1999)) as defined by Dice et al. (Ecology 26:297-302 (1945)).

The Examiner repeats the arguments presented in the Final Action as the basis for rejecting the claimed invention and reiterates her position that Loh et al. teaches the use of AFLP to analyze the genetic relationships in ornamental plants generally. (Examiner's Answer, page 16 and 24). Applicants respectfully disagree.

The Loh et al. reference is solely concerned with *Caladium* and the applicability of AFLPs to *Caladium* cultivars. Loh et al. states that AFLP has the potential for precisely characterizing and identifying particular caladium cultivars as well as for the registration of new cultivars. (Loh et al., abstract). Loh et al. provides no teaching or suggestion that AFLP analysis could be applied to poinsettia or even a more general statement that AFLP analysis would be suitable for the study of ornamental plants other than *Caladium*. Appellants respectfully submit that the Loh et al. investigators do not make such a statement because one of ordinary skill in the art would reasonably understand that there would be no reasonable expectation of success in using AFLP in any other particular species based on their work solely with *Caladium*. It is the Examiner's unsupported conclusion that AFLP could be used generally to analyze genetic relationships in ornamental plants generally and not a conclusion based on what can be found in the cited references, in the prior art generally or by what would be the common sense of one of ordinary skill in the art. Therefore, this rejection cannot be maintained.

The Examiner further states that "the ordinary artisan would have been motivated to substitute one known method of determining genetic relationship, RAPD as taught by Ling, for

another known equivalent method of determining genetic relationship, AFLP as taught by Loh to obtain the predictable results of estimating the genetic relationship between a poinsettia plant and known poinsettia plant." Examiner's Answer, page 18, emphasis added. Appellants submit that it is not the predictability of the results of estimating the genetic relationship using AFLP that is relevant to the present rejection. The issue that is relevant to the present rejection is the predictability of whether AFLP would work at all in poinsettia and such a prediction cannot be based on the cited references or any other references discussing AFLP use in other divergent species such as *Caladium*. The Examiner's conclusion that AFLPs would be predictably useful in poinsettia can only be based on knowledge of the present application. Furthermore, in this statement the Examiner is contending that RAPD and AFLP methods are equivalent; however, later it is argued that another method of genetic analysis, SSR, is a different technique than AFLP and cannot be used as an indicator for the predictability of AFLP in poinsettia. Examiner's Answer, page 20-21. Appellants are not clear on what basis the Examiner can extrapolate between RAPD and AFLP while Appellants discussion comparing the application of SSR and AFLP in poinsettia is dismissed.

In response to Appellants' arguments that one of ordinary skill in the art would not have concluded that the methods of Loh et al. with *Caladium*, would have had a reasonable expectation of success if applied to an asexually reproduced and thus, much less genetically diverse plant, such as poinsettia, the Examiner states that AFLP was shown to be capable of detecting polymorphisms among very similar genomic variations. To support this conclusion, the Examiner cites two references applying AFLP to the bacteria *E. coli* and *B. anthracis* (Arnold et al. and Keim et al., respectively).

Appellants assert that one of ordinary skill in the art would not consider a reference describing the application of a particular method for estimating the genetic diversity in a bacterial genome to be at all relevant to that for a plant genome. *Arabidopsis thaliana* has the smallest plant genome with a genome size of 115 million bp as compared to *E. coli* and *B. anthracis*, which have genome sizes of approximately 5 million bp. Rice has a genome size of approximately 390 million bp, while poinsettia has a genome size of approximately 1270-1613 million bp. Clearly, one of skill in the art when assessing a technique for genetic analysis in

plants would not consider results from bacteria to be predictable of the type of results that one might achieve in the much larger genomes of plants, much less consider it predictive of the type of results one might expect in poinsettia.

The Examiner then states that the evidence provided in the Declaration by Dr. Moyer of the comparison of SSR analysis to provide unpredictability of assessing genetic relationships among cultivars is not persuasive as Russell et al. teaches that SSR and AFLP are not equivalent methods or indicators of genetic diversity. (Examiner's Answer, page 21). Appellants provided Russell et al. to show that SSR can be applied to many plant species successfully. In Russell et al. the SSR, RAPD, RFLP and AFLP methods were applied to barley accessions. Russell et al. found that "[a]ll of the approaches were able to uniquely fingerprint each of the accessions. (Russell et al., abstract). The Examiner further states that Russell et al. teaches that AFLP is the most efficient method (*Id.*). However, even if true, efficiency is not the issue. Instead, the issue that Russell et al. addresses in the context of the present application is that it shows that SSR is useful for genetic analysis of barley accessions whereas in contrast it is not useful for poinsettia, once again demonstrating that **one cannot predict the usefulness of any particular method of genetic analysis based on its usefulness in another distinct species.**

Additionally, the Examiner further states that Russell et al. provides evidence that SSRs do not seem to be particularly useful for assessing genetic relationships among cultivars. (*Id.*). However, Russell et al. also states that the ideal fingerprinting assay should require no prior sequence knowledge and while only AFLPs and RAPDs meet these requirements the lack of comparative information at each assayed locus (due to dominance) precludes an accurate assessment of true genetic relationship. (Russell et al., 712, last paragraph; emphasis added). Thus, in the context of barley only, Russell et al. questions the usefulness of each of these methods for genetic analysis. Therefore, one of ordinary skill in the art would not reasonably conclude that results of applying any particular method of genetic analysis (including AFLP, RFLP, RAPD, SSR) in a particular plant species other than the species at issue would provide a reasonable expectation of success for that method in the plant species at issue.

With regard to the Pejic et al. reference, the Examiner states that it teaches that AFLP is the most efficient marker system. (Examiner's Answer, pages 21-22). The Examiner then states

"[t]hus, the method of AFLP is more effective and thus more sensitive than SSR." (*Id.*) However, once again, the issue is not the efficiency of the AFLP system and furthermore, efficiency is not a determinant of sensitivity. (*Id.*). Nowhere in Pejic et al. can a statement be found that AFLP is a more sensitive assay than SSR. This is simply an assertion of the Examiner for which no evidence is provided in support. In fact Pejic et al. found that for maize both "SSR and AFLP technologies can replace RFLP in genetic similarity studies because of their comparable accuracy in genotyping inbred lines selected by pedigree." (Pejic et al., abstract) In contrast, in poinsettia, AFLPs, but not SSRs, were found to work successfully. **Until the work of the Appellants the success of the application of AFLPs to poinsettia could not have been predicted.**

Accordingly, in view of the foregoing, Appellants submit that the outstanding rejection over Ling et al. in view of Loh et al. and Dice is legally insufficient to establish a *prima facie* case of obviousness and should be withdrawn.

B. Claims 1, 3, 5-7, 21, 23, 24, 30, 63 and 69 are not obvious under 35 U.S.C. § 103(a) over Ling et al., in view of Barcaccia et al. (J. Horticultural Science and Biotechnology 74:243-50, (1999)) as defined by Dice et al.

The Examiner states that the "response repeatedly uses the argument that the genetic relationship between poinsettias and rice, geraniums, willows, etc. is distinct, however none of the rejections or the claims require distinguishing the genetic relationship between poinsettia's or other species or require that the genetic relationship be the same. The rejections of record establish that it would be obvious to use AFLP in the method of distinguishing a genetic relationship between poinsettia as taught by Ling et al." (Examiner's Answer, page 27.) Appellants respectfully disagree with Examiner's conclusions regarding Appellants' arguments and the obviousness rejection.

As an initial matter, Appellants are not suggesting that the rejection requires that the genetic analysis be between the different species discussed in the cited references. Appellants arguments instead show that the use of any particular method of genetic analysis (including

AFLPs) in species that differ from the plant species at issue (e.g., poinsettia) fails to provide one of ordinary skill in the art any motivation or reasonable expectation of success of the application of that particular method (e.g., AFLPs) to poinsettia. Each of the plants discussed in the cited references have genomes that are diverse from one another with their own particular characteristics which will influence the success or failure of the application of any particular method of genetic analysis. One of ordinary skill in the art simply would not reasonably rely on results in distinct unrelated species to provide a reasonable expectation of success in poinsettia. The fact that SSRs can be applied to many plant species successfully, but not poinsettia, makes this point clear.

With regard to the Barcaccia et al. reference, the Examiner states that Barcaccia et al. teaches comparing an unknown plant to a known cultivar. (Examiner's Answer, page 27). This is incorrect. All of the plants used in the Barcaccia et al. study were unknown. They were picked up either at a crime scene or in a suspect's place of residence with no information provided regarding the species or cultivar status of these plants. Therefore, none of the plants in Barcaccia et al. could be considered to be "known" genetically or otherwise. The Examiner states that Barcaccia et al. teaches that AFLP analysis is successful in identifying genetic relationships between plants and that Barcaccia et al. demonstrates that AFLP was known predictable method to estimate genetic relationships. (Examiner's Answer, page 26). However, in order to be able to make any statement regarding the ability of a particular technique to estimate a genetic relationship, to assess the breeding history, to determine whether one particular plant is a representative of a known cultivar or to distinguish between one cultivar from another known cultivar, it is necessary to have information regarding the genetic origin of the reference plant(s). Accordingly, because Barcaccia et al. utilizes only geranium plants of entirely unknown genetic origin, one of ordinary skill in the art would not have concluded, based on Barcaccia et al., that AFLP analysis was successful in distinguishing even geranium cultivars, much less that the same technique could be applied successfully to distinguish between and among poinsettia cultivars.

The Examiner further states that Barcaccia et al. was not cited to demonstrate the relationship between poinsettia and geraniums or provide evidence of a relationship between poinsettia and geranium. (Examiner's answer, page 27). Appellants contend that the outstanding

rejection draws a direct connection between work in geranium and the present invention in poinsettia. Final Action, page 22. This rejection is based on the premise that there would have been motivation to combine work done in geranium (Barcaccia et al.) with work done in poinsettia (Ling et al.), and, further, that the use of AFLP analysis in geranium would render obvious the use of AFLP analysis in poinsettia (this is the same premise upon which every obviousness rejection in the present case is based). Appellants' arguments regarding the distinctness of geranium and poinsettia are directed to the legally deficient foundation of the outstanding rejection; because there is no genetic relationship between geranium and poinsettia, (1) there would be no motivation to combine the cited references, and (2) even if the references were so combined there would not have been any reasonable expectation of success with respect to the present invention. Accordingly, the outstanding rejection over Ling et al. in view of Barcaccia et al. and Dice is legally insufficient to establish a *prima facie* case of obviousness and should be withdrawn.

C. Claims 1, 3, 5-7, 21, 23, 24, 30, 63 and 69 are not obvious under 35 U.S.C. § 103(a) over Ling et al., in view of Sukhwinder et al. (Crop Improvement 25:15-20 (1998)) as defined by Dice et al.

The Examiner states that "Sukhwinder et al. teaches that although other fingerprinting methods such as RFLP and RAPD assays had been commonly used to discriminate *various* cultivars, the new technique of using AFLP 'combines reliability and robustness of RFLP and strength of PCR techniques. Therefore, one of skill in the art would have been motivated to use the method of Sukhwinder et al. with poinsettia cultivars as Sukhwinder et al. suggest that this new technique can discriminate *various* cultivars, which would include poinsettia cultivars." (Examiner's Answer, page 30).

Contrary to the Examiner's assertion, Sukhwinder et al. discusses AFLP analysis solely as it relates to rice cultivars and wild rice species. (Sukhwinder et al., abstract, page 18-19). Nowhere in Sukhwinder can support be found for the statement that the "new technique can discriminate various cultivars" other than rice cultivars. The discussion of AFLPs in Sukhwinder et al. is limited to that of rice. Further, we note that Sukhwinder et al. states that with the exception of just one of the cultivars studied all of the rice cultivars were grouped into one

cluster. Thus, it is not clear from the Sukhwinder et al. study that AFLPs effectively discriminates between various rice cultivars much less suggests that AFLPs could discriminate between various poinsettia cultivars. Thus, similar to the previously discussed references concerning AFLP in *Caladium* and geranium, Sukhwinder et al. is not relevant to poinsettia and would not have provided the motivation to combine or any reasonable expectation of success with respect to the claimed invention that are legally sufficient to maintain the present rejection. Accordingly, Appellants respectfully request that this rejection be withdrawn.

D. Claims 1, 3, 5, 6, 21, 23, 30, 63 and 69 are not obvious under 35 U.S.C. § 103(a) over Ling et al., in view of Barker et al. (Genome 42:173-183 (1999)) as defined by Tulloss (Offprint from Palm and Chapel, eds., (1997)).

The Examiner reiterates the contention that each of the references cited that use AFLP technology were cited not to compare the relationship between a poinsettia to the other species but to demonstrate that at the time the invention was made it would have been obvious to use the known predictable method of AFLP to generate DNA fingerprints with method of Ling et al. which establishes a genetic diversity of poinsettia plants by use of RAPD." (Examiner's Answer, pages 31-32).

Appellants again note that while the Examiner contends there is no attempt to compare poinsettia to other species, the present rejections do in fact draw a direct connection between work in willow, *Caladium*, geranium, and rice, and the present invention in poinsettia. These rejections are based on the premise that there would have been motivation to combine work done in geranium (Barcaccia et al.), *Caladium* (Loh et al.), rice (Sukhwinder et al.) and/or willow (Barker et al.) with work done in poinsettia (Ling et al.), and, further, that the use of AFLP analysis in these various species would render obvious the use of AFLP analysis in poinsettia. Appellants' arguments regarding the distinctness of poinsettia and these other plant species are directed to the legally deficient foundation of the outstanding rejection; because there is no genetic relationship between these species and poinsettia, (1) there would be no motivation to combine the cited references, and (2) even if the references were so combined there would not have been any reasonable expectation of success with respect to the present invention.

Furthermore, with regard to the statement in the Examiner's Answer that "there is no evidence of record that AFLP would not have worked for poinsettias." (Examiner's Answer, page 32), Appellants respectfully submit that Appellants are not required to show that AFLP would not work for poinsettia. This would be contrary to the present application. However, Appellants have presented sufficient evidence to show that each of the various techniques used for genetic analysis must be evaluated separately for each species of interest and that one of ordinary skill in the art would reasonably consider the results of applying AFLP to any particular species, including poinsettia, unpredictable until tested. Therefore, there would be no motivation to combine the cited references and even if the references were so combined there would not have been any reasonable expectation of success with respect to the present invention.

Accordingly, similar to the outstanding rejections over Ling et al. in view of Loh. et al., Barcaccia et al., and/or Sukwinder et al. and Dice, the rejection over Ling et al. in view of Barker et al. and Dice is legally insufficient to establish a *prima facie* case of obviousness and should be withdrawn.

II. Conclusion

For the reasons set forth above and in Appellants' Brief on Appeal, Appellants request reversal of the rejections of the claims, allowance of the claims, and passing of the application to issuance.

No fee is believed due. However, the Commissioner is hereby authorized to charge any deficiency, or credit any refund to our Deposit Account No. 50-0220.

Respectfully submitted,



Alice M. Bonnen

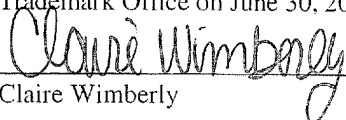
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